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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,121	10/31/2003	Dominic Cosgrove	249.0007 0101	8958

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EXAMINER	
HADDAD, MAHER M	
ART UNIT	**PAPER NUMBER**
1644	

MAIL DATE	DELIVERY MODE
02/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.**	**Applicant(s)**	
	10/698,121	COSGROVE, DOMINIC	
	Examiner	**Art Unit**	
	Maher M. Haddad	1644	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 16 January 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *None*.
   Claim(s) objected to: *None*.
   Claim(s) rejected: *1-3,5-8,10-13,15,17,21,23,25,27,28 and 43-59*.
   Claim(s) withdrawn from consideration: *60-66*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☒ Other: IDS filed 1/16/07.

Continuation of 11. does NOT place the application in condition for allowance because: Because Lin et al reference teaches only anti-collagen type XVIII antibody but not anti-collagen type XIII antibody, the previous rejection of claims under 35 U.S.C. 103(a) is hereby withdrawn.

Because Lin et al reference teaches only anti-collagen type XVIII antibody but not anti-collagen type XIII antibody, the previous rejection of claims under provisionally rejected on the ground of nonstatutory obviousness-type double patenting is hereby withdrawn.

1. Claims 43-44 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection.

A. The phrase "a kidney disease associated with an accumulation of a1b1 integrin positive monocytes in the inerstitium, the method comprising administering to the patient an antibody to collagen XIII" claimed in claim 43,

B. The phrase "a progressive renal fibrosis, the method comprising administering to the patient an antibody to collagen XIII" claimed in claim 44,

represents a departure from the specification and the claims as originally filed for the same reasons set forth in the previous Office Action mailed 10/13/06.

Applicant's arguments, filed 1/16/07, have been fully considered, but have not been found convincing.

Applicant points to original claims 7 and 11 for support. However, neither claim 7 nor claim 11 provide support of a genus of "kidney diseases" or for a subgenus of "progressive renal fibrosis". While Applicant points to original claim 11 to support, however, claim 11 does not provide support for "progressive" renal fibrosis.

2. . Claims 1-3, 5-8, 10-13, 15, 17, 21, 23, 25, 27-28 and 43-59 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the same reasons set forth in the previous Office Action mailed 10/13/06.

Applicant's arguments, filed 1/16/07, have been fully considered, but have not been found convincing.
Applicant submits that compliance with the enablement requirement does not turn on whether an example is disclosed. Further, Applicant submits that the specification provides adequate enablement for the claimed methods. Applicant contends that he does not understand the relevance of the assertion regarding the skilled medical practitioner would not be able to identify all chronic inflammatory diseases or conditions associated with the interaction of COllagen XIII with alpha1 beta 1 integrin monocytes based on the disclosure. Further Applicant submits that chronic inflammatory diseases or conditions are well known and identifiable by the skilled practitioner.

Again, the influence of a scientific theory should depend on its empirical and demonstrable aspects and not its underlying logic. Yet such empirical and demonstrable aspects of the claimed method of treating any inflammation, condition or kidney disease with the anti-Collagen XIII antibodies are lacked in the instant specification. No working empirical data demonstrating that the anti- Collagen XIII antibodies would treat or reduce any inflammation is disclosed. The specification provides neither working examples nor correlation between the disclosed chronic inflammatory treatment and the claimed method for treating or reducing the inflammation to establish practical methods of treating renal fibrosis or crescentic glomerulonephritis with the claimed anti-Collagen XIII antibodies. The state of the art is that current treatments of inflammation/conditions associated with the interaction of Collagen XIII with a1b1-integrin positive monocyte, such as renal fibrosis and crescentic glomerulonephritis, is in fact unknown and untested. What are the underlying adherent and physiologic bases of the therapeutic effect of anti-Collagen XIII antibodies, which decreases the rate of efflux of a1b1 integrin positive monocytes into the interstitial space, in the treatment of renal fibrosis or crescentic glomerulonephritis. In re Fisher, 166 USPQ 18 indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute.

Although Applicant's specification describes a reduction in monocytes efflux for mice treated with a purified a1b1 integrin. Further the specification shows that Collagen XIII immunoprecipated with purified a1b1 integrin, Collagen XIII is induced on vascular endothelial cells from chronically inflamed kidneys and Collagen XIII and CD31 co-localized in the Alport renal cortex see pages 39-40), but their significance is unclear. Based on Collagen XIII location in tissues and cultured cells and its binding properties, Applicant concludes that the scope of the anti-Collagen XIII antibodies have biological activity to treat inflammatory disorders including renal fibrosis, crescentic glomerulonephritis or any condition associate with monocytes accumulation including kidney diseases and be provided as pharmaceutical compositions to subjects including human to effectively treat inflammatory disorders. However, there is no correlation on this record between in vitro experiments and a practical method of in vivo use in currently available form for humans or animals. It is not enough to rely on in vitro studies where a person having ordinary skill in the art has no basis for perceiving those studies as constituting recognized screening procedures with clear relevance to methods of in vivo use in humans or animals (emphasis added). Ex parte Maas, 9 USPQ2d 1746. There must be a rigorous correlation of pharmacological activity between the disclosed in vitro use and an in vivo use to establish practical methods of in vivo use.

Finally, since the claims are directed to a method of treating a patient having a chronic inflammatory disease associated with the interaction of Collagen XIII with a1b1 integrin positive monocytes, the skilled medical practitioner would not be able to identify all the

chronic inflammatory diseases or conditions associated with this interaction of Collagen XIII with a1b1 integrin positive monocytes based on the disclosure. The skilled medical practitioner would not look at a chronic inflammatory disease and characterize the disease to be associated with the interaction of Collagen XIII with a1b1 integrin positive monocytes. Besides the specific diseases recited in claim 3, the medical practitioner would not know which chronic inflammatory disease would full within the claimed invention.

Maher M. Haddad
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PRIMARY EXAMINER
1644
1/29/07